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United States Congress Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Hearing on Science and Mission at Risk: FDA's Self-Assessment
Washington, D.C.
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Mr. Chairman and Members of the Committee: Thank you for the opportunity to testify before you this morning on "FDA Science and Mission at Risk," the report of the Subcommittee on Science and Technology to the FDA Science Board.

My name is Dr. Dale Nordenberg and I am testifying this morning on behalf of the Subcommittee on Science and Technology of the FDA Science Board. I am a pediatrician and a Centers for Disease Control (CDC)-trained medical epidemiologist. My area of expertise is health information technology, and I have approximately 25 years of experience in this field. I was invited to participate in the FDA Subcommittee on Science and Technology while I was the Associate Director for Informatics at the National Center for Infectious Diseases, CDC. While I resigned from the CDC four months ago to become a managing director with PricewaterhouseCoopers LLP, I am not here this morning on behalf of PricewaterhouseCoopers nor does my testimony in any way reflect the policies or positions of PricewaterhouseCoopers.

Information Technology at the FDA

Information technology at the FDA has three different purposes. First, information technology at the FDA provides an information and

communications infrastructure that is deployed to serve the needs of programs at the FDA and thus serves an operational role. Examples of this would include the computer network, e-mail system, financial and other administrative systems, and Internet connectivity.

Second, information technology at the FDA is encountered in regulated medical products, such as emerging wireless devices that can monitor heart rate and rhythm in real time as well as provide electrical shocks to the heart to treat abnormal rhythms. In this instance, the FDA must have the scientific and technical capability to review and regulate these products.

Finally, information technology at the FDA is a science and discipline that FDA scientists must use to assess the efficacy and safety of medical products as part of the regulatory mission of the Agency. This would include data and information modeling, analytic activities, implementation of evolving health information technology standards and health information exchanges to support pre-market clinical trials and post-market pharmacovigilance. This arena is often referred to as healthcare or medical informatics.

Information technology is absolutely critical to ensure data access, management and analytics related to inspections for food, drug and device manufacturing sites and for tracking foodborne disease outbreaks. The FDA must have the expertise to deploy or manage information technology in all of these three contexts in order to successfully support the regulatory science that enables the Agency to fulfil its regulatory mission.

Our subcommittee found that "an information crisis is putting the FDA mission at risk."[1] It further reported that "the IT situation at FDA is problematic at best — and at worst it is dangerous."[2]

While the subcommittee would like to acknowledge that it identified recent promising trends in IT activity priority setting at the FDA, the rate of progress is unacceptably slow. At this pace, there is a dual and compounding risk. Specifically, the FDA is struggling with the too-slow modernization of its current infrastructure while it is simultaneously challenged to develop the capability to manage the risk from rapidly emerging sciences, particularly genomics as you have heard from Dr. Fitzgerald; technology and threats such as bioterrorism; and globalization leading to a massive increase in imported products. Ultimately, the FDA must leverage regulatory and information science to support industry innovation while assuring the efficacy and safety profiles of products that it regulates.

Leadership and people

The subcommittee commends the dedication and commitment of FDA's IT professionals. Besieged by increasing complexity, there is a critical need to assist them by establishing professional development plans and providing access to continuing education. In addition, the Agency should explore extramural partnerships to help provide the required IT expertise.

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[1] "FDA Science and Mission at Risk" ("Report"), page 46
[2] Report, page 5

The subcommittee was surprised to discover that the FDA has had multiple chief information officers in recent years. Given the lack of consistent leadership in information technology, it is clear that even the basic IT infrastructure is presenting significant risk to the FDA's regulatory mission.

Information Technology Infrastructure

The subcommittee report states, the "FDA IT infrastructure is obsolete, unstable, and lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services."[3] Specifically, the FDA technology infrastructure was burdened with 80 percent of network servers beyond the recommended life of the machine. Many people we interviewed described an environment of computers and servers distributed around the agency unsecured and without adequate recovery practices in the event of a natural disaster or other crisis. Many staff reported having had experienced loss of data. As a simple example of the consequences of an unstable technology infrastructure, the FDA's participation in the national *E.Coli* O157 outbreak in 2006 was hampered by outages in the FDA e-mail system that depends on the outdated FDA technology infrastructure.

Access to Data and Information (including data sharing networks)

The regulatory mission of the FDA is dependent on regulatory science; the discipline and methodologies used to evaluate the efficacy and safety of the regulated products evaluated by the FDA. Regulatory science, and thus the

[3] Report, page 51

mission of the FDA, is dependent on timely access to quality data and information.

Our subcommittee found that "the FDA's current critical information supply chains are, at best, inefficient, cost intensive and prone to promote errors in regulatory science due to the inability to access, integrate and analyze data. Incredibly, critical data resides in large warehouses sequestered in piles and piles of paper documents."[4]

In addition, the subcommittee found that "reports of product dangers are not rapidly compared and analyzed, inspectors' reports are still hand written and slow to work their way through the compliance system, and the system for managing imported products cannot communicate with Customs and other government systems (and often miss significant product arrivals because the system cannot even distinguish, for example, between road salt and table salt)."[5]

The FDA must invest in the development of both intramural and extramural health information exchange infrastructures for data sharing between health stakeholders such as payers, providers, pharmacies and patients to support all aspects of the critical path for medical therapeutics and devices, food safety, and other regulated products.

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[4] Report, page 48
[5] Report, page 5

Emerging Sciences and Threats

The subcommittee identified emerging sciences and threats as a major risk to its regulatory mission. Briefly, these emerging sciences and threats include: pan-omics, wireless healthcare, nanotechnology, medical imaging, telemedicine platforms, electronic health records – especially as they interface with medical devices – bioterrorism and globalization leading to the rapidly increasing number of imported products under FDA regulation.

The subcommittee found that the "FDA lacks the capability to manage the complex data and information challenges associated with rapid innovation, such as new data types, data models and analytic methods."[6] The proposed Incubator for Innovation in Regulatory and Information Science, described by Dr. Garret Fitzgerald, is an excellent environment to ensure that information sciences and information technology professionals at the FDA perceive and respond to the regulatory needs of rapidly evolving sciences and threats to fulfill its regulatory mission.

Budget Recommendations

The subcommittee believes that the information technology budget at the FDA must be increased. Based on publicly available information, the overall IT budget for the FDA is approximately $200 million — compared to approximately $500 million for the CDC, although the FDA regulates $1 trillion dollars in consumer products and 80 percent of the nation's food supply and is

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[6] Report, page 50

responsible for monitoring hundreds of thousands of manufacturing sites distributed globally.

Increasing the budget would allow the FDA to upgrade and modernize its technology, support development of its professional staff, establish the information systems it needs to fulfill its mission and stimulate the development of data and information sharing among academic and private sector stakeholders to support innovation and regulation.

In summary, the subcommittee engaged in this endeavor with a strong belief that "The FDA, as much as any public or private sector institution in this country, touches the lives, health and wellbeing of all Americans and is integral to the nation's economy and its security."[7] Given this, "the nation is at risk if FDA science is at risk."[8] Without significant investment in information technology at the FDA, our subcommittee is firmly convinced that both the public's health and the nation's economic competiveness are at great risk.

It is the hope of the subcommittee that action will be taken to ensure the robustness of the FDA and thus its ability to fulfil its regulatory mission to protect the public's health and helping to speed innovation in regulated industries.

Thank you, Mr. Chairman, for the opportunity to testify this morning.

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[7] Report, page 1
[8] Report, page 2